

The carbolic ointment was alleged to be adulterated in that it purported to be and was represented as a drug the name of which, "Phenol Ointment" or "Ointment of Carbolic Acid," is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from or its quality fell below the standard set forth therein since the compendium provides that phenol ointment or ointment of carbolic acid shall contain not less than 1.8 percent of carbolic acid, whereas the article contained carbolic acid in amounts varying from 1.56 percent to 1.69 percent, and its difference in strength and quality from the standard was not plainly stated on its label. It was alleged to be misbranded in that the statements "Carbolic Ointment U. S. P.," and "Net Wgt. 1 Oz.," borne on its labels, were false and misleading since the article did not conform with the requirements of the Pharmacopoeia, and its containers did not contain 1 ounce net weight of the article but contained a smaller amount.

On June 26, 1944, a plea of guilty having been entered on behalf of the defendant, the court imposed a fine of \$200 on each of 6 counts. Payment of the fine on 5 of the counts was suspended.

1212. Adulteration of digitalis tablets and tincture of digitalis. U. S. v. Direct Sales Co., Inc. Plea of guilty. Fine, \$300. (F. D. C. No. 11336. Sample Nos. 21817-F, 21818-F.)

On January 24, 1944, the United States attorney for the Western District of New York filed an information against the Direct Sales Co., Inc., Buffalo, N. Y., alleging shipment of a quantity of the above-named products on or about January 19, 1943, from the State of New York into the State of Pennsylvania.

The digitalis tablets were alleged to be adulterated in that each tablet purported and was represented to possess a potency equivalent to not more than 0.62 digitalis unit, as defined in the United States Pharmacopoeia, whereas each tablet possessed a potency equivalent to not less than 1.35 digitalis units.

The tincture of digitalis was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from the official standard since 1 cc. of the article possessed a potency equivalent to not less than 1.86 U. S. P. digitalis units, which is 86 percent in excess of the potency of the official product, and its difference in strength was not plainly stated on its label.

On February 14, 1944, a plea of guilty having been entered on behalf of the defendant, the court imposed a fine of \$150 on each of 2 counts, a total fine of \$300.

1213. Adulteration of Bevitin (thiamine hydrochloride). U. S. v. 3,000 Ampuls and 12,000 Ampuls of Bevitin Brand of Thiamine Hydrochloride. Decrees of condemnation. Portion of product ordered released under bond; remainder ordered destroyed. (F. D. C. Nos. 11289, 11290. Sample Nos. 29634-F, 29635-F.)

On December 9 and 20, 1943, the United States attorneys for the Eastern District of Missouri and the Southern District of Georgia filed libels against 3,000 ampuls of the above-named product at St. Louis, Mo., and 12,000 ampuls of the same product at Savannah, Ga., alleging that the article had been shipped on or about November 3, 1943, from Brooklyn, N. Y., by the Pro-Medico Laboratories, Inc.; and charging that it was adulterated.

The article was alleged to be adulterated in that its purity and quality fell below that which it purported and was represented to possess, i. e., "Intravenous—Intramuscular," since it was not suitable for parenteral use because of contamination with undissolved material.

On February 24 and March 4, 1944, the Pro-Medico Laboratories, Inc., having appeared as claimant for the Georgia lot and having admitted the allegations of the libel, and no claimant having appeared for the Missouri lot, judgments of condemnation were entered and the Georgia lot was ordered released under bond to be brought into compliance with the law under the supervision of the Food and Drug Administration, and the Missouri lot was ordered destroyed.

1214. Adulteration of suprarenalin solution. U. S. v. 432 Vials of Suprarenalin Solution. Default decree of condemnation and destruction. (F. D. C. No. 11519. Sample No. 65902-F.)

On January 3, 1944, the United States attorney for the Southern District of New York filed a libel against 432 vials of suprarenalin solution at New York, N. Y., alleging that the article had been shipped on or about November 12 and 26, 1943, by the Armour Laboratories, Chicago, Ill.; and charging that it was adulterated. The article was labeled in part: "Suprarenalin Solution 1 : 1,000 A brand of solution of epinephrine hydrochloride U. S. P. Sterile—For Hypodermatic Use."

The article was alleged to be adulterated in that it purported to be and was represented as a drug, epinephrine hydrochloride ampuls, the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since the article was not free from undissolved material.

On February 28, 1944, no claimant having appeared, judgment of condemnation was entered and it was ordered that a portion of the product be released to the Federal Security Agency, and that the remainder be destroyed.

1215. Adulteration of pentothal sodium with redistilled water. U. S. v. 1,866 Packages of Pentothal Sodium with Redistilled Water. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 11264. Sample No. 57293-F.)

On December 11, 1943, the United States attorney for the Northern District of New York filed a libel against 1,866 packages of the above-named product at Schenectady, N. Y., alleging that the article had been shipped on or about November 12, 1943, from Chicago, Ill., by the Abbott Laboratories; and charging that it was adulterated. The article was labeled in part: "Pentothal Sodium * * * And Chemically Pure Water, 50 CC. * * * Dissolve the contents of the ampoule of Pentothal Sodium in the 50 cc. of sterile chemically pure water * * * For intravenous injection." The ampul of water was labeled "Chemically Pure Water (Ampul of Redistilled Water, N. F.)."

The article was alleged to be adulterated in that the water purported to be and was represented as redistilled water, a drug the name of which is recognized in the National Formulary, an official compendium, but its quality and purity fell below the standard set forth therein since the water was not free from undissolved material.

On March 15, 1944, the Abbott Laboratories, claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond to be brought into compliance with the law, under the supervision of the Food and Drug Administration.

1216. Adulteration of atabrine and distilled water combination packages. U. S. v. 1,050 Cartons and 2,473 Cartons of Atabrine Dihydrochloride with Distilled Water. Decrees of condemnation. Portion of product ordered released under bond; remainder ordered destroyed. (F. D. C. Nos. 11799, 11800. Sample Nos. 10695-F, 12665-F.)

On February 11 and 21, 1944, the United States attorneys for the Northern District of California and the Western District of Washington filed libels against 3,523 cartons of the above-named product at Oakland, Calif., and Seattle, Wash., respectively, alleging that the article had been shipped on or about December 17 and 23, 1943, from Albany, N. Y., by the Winthrop Chemical Co., Inc.; and charging that it was adulterated. The article was labeled in part: (Carton) "5 Ampuls 0.2 Gm. Atabrine Dihydrochloride * * * With 5 Ampuls, 10 cc. Size Sterile Distilled Water."

The article was alleged to be adulterated in that it purported to be and was represented as a drug, "Sterilized Distilled Water" and "Water for Injection," the names of which are recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since the Pharmacopoeia provides that sterilized distilled water (and water for injection) is a clear liquid, whereas the article was contaminated with undissolved material.

On March 17, 1944, the Winthrop Chemical Co., Inc., having appeared as claimant for the California lot, judgment of condemnation was entered and the product was ordered released under bond to be brought into compliance with the law, under the supervision of the Food and Drug Administration. On August 19, 1944, no claimant having appeared for the Seattle lot, judgment of condemnation was entered and the product was ordered destroyed.

1217. Adulteration of sterile distilled water. U. S. v. 2 Packages and 10 Packages of Sterile Distilled Water. Default decree of condemnation and destruction. (F. D. C. No. 11685. Sample No. 51270-F.)

On January 24, 1944, the United States attorney for the District of Massachusetts filed a libel against 2 packages, each containing 25 ampuls, and 10 packages, each containing 10 ampuls, of the above-named product at Worcester, Mass., alleging that the article had been shipped on or about August 12, 1943, from Philadelphia, Pa., by the Stratford-Cookson Co.; and charging that it was adulterated.